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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,293	04/19/2006	Hitoshi Obata	2006-0551A	4490

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EXAMINER	
GREEN, ANTHONY J	
ART UNIT	PAPER NUMBER
1793	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,293	OBATA ET AL.	
	Examiner	Art Unit	
	Anthony J. Green	1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 April 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of certain non-proteinaceous materials, does not reasonably provide enablement for the use of any and all types of non-proteinaceous materials. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims recite an agent for inhibition of ice crystal growth comprising a non-proteinaceous substance. This encompasses any non-proteinaceous substance. However, the specification only teaches the use of certain types. Such a limited disclosure does not support the breadth of the instant claims.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by PCT International Application No. WO 99/18169.

The reference teaches, in the claims, and the examples, a method of inhibiting growth of crystals by applying to said material a plurality of molecules in an amount effective for inhibiting ice crystal growth wherein said molecules comprise an aliphatic moiety bearing at least two substituents that simultaneously form hydrogen bonds with ice. The moiety is selected from 1, 3-cyclohexanediol residue, a cis,cis-1,3,5-cyclohexanetriol residue etc. (see claim 2). Applicants attention is also drawn to claims 4-22 and also see page 25, line 1 - page 29, line 10.

The instant claims appear to be met by the reference as they teach the formation of various non-proteinaceous agents for inhibition of ice-crystal growth. As for the properties recited in the claims, these appear to be inherent properties possessed by the agents of the reference absent evidence showing otherwise. Applicant should note that the limitation of "wherein an aqueous solution of the non-proteinaceous substance in a concentration of 10mg/ml" is not a positive claim limitation as it is not a required limitation as the claims are only drawn to the agent itself.

5. Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Brockbank et al (US Patent Application Publication No. US 2003/0180704 A1.

The reference teaches, in the claims and in columns [0058]-[0061], a method of inhibiting growth of ice crystals, comprising identifying a material requiring inhibition of growth of ice crystals, and applying to the material, in an amount effective for inhibiting ice crystal growth on or in said material, one or more ice-controlling materials selected from the group consisting of 1,2-cyclohexanediol, 1,3-cyclohexanedione, 1,4-cyclohexanedione, 1,2-cyclohexandione, 1,4-cyclohexanedimethanol, a mixture of 1,4-cyclohexanediol with one or more of 1,3,5-cyclohexanetriol, 1,3-cyclohexanediol, 1,2-cyclohexanediol, 1,3-cyclohexanedione, 1,4-cyclohexanedione, 1,2-cyclohexandione and 1,4-cyclohexanedimethanol, charged derivatives of the ice-controlling materials that include one or more charged moieties therein, and polymers including one or more of the ice-controlling materials in the chain thereof. The ice material may be a polymer including one or more of the ice-controlling materials in the chain thereof, the ice-controlling materials being present in the chain in an amount effective to inhibit ice crystal growth (see claims 1 and 3). Paragraphs [0058]-[0061] and claims 5-9, teaches the types of materials that may be treated with the ice crystal growth inhibitors which include frozen foods, crops, various surfaces etc.

The instant claims appear to be met by the reference as they teach the formation of various non-proteinaceous agents for inhibition of ice-crystal growth. As for the properties recited in the claims, these appear to be inherent properties possessed by the agents of the reference absent evidence showing otherwise. Applicant should note that the limitation of "wherein an aqueous solution of the non-proteinaceous substance

in a concentration of 10mg/ml" is not a positive claim limitation as it is not a required limitation as the claims are only drawn to the agent itself.

6. Claims 1-3, 5-6 and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Liang et al (US Patent No. US 2002/0144804 A1).

The reference teaches, in the abstract and the claims, a kinetic ice inhibitor in an amount effective to kinetically inhibit the nucleation and growth of ice crystals within said water when said working fluid is subjected to temperatures below 0.degree. C. The kinetic ice inhibitor comprises a substantially water-soluble polymer such as a polymer is selected from the group consisting of: polyvinylpyrrolidone (PVP), polyvinylcaprolactam (PVCAP), poly(vinylpyrrolidone-vinylcaprolactam) (VPNC), and poly(vinylpyrrolidone-vinylcaprolactam-dimethylaminoethyl) (VC-713).

The instant claims appear to be met by the reference as they teach the formation of various non-proteinaceous agents for inhibition of ice-crystal growth. As for the properties recited in the claims, these appear to be inherent properties possessed by the agents of the reference absent evidence showing otherwise. Applicant should note that the limitation of "wherein an aqueous solution of the non-proteinaceous substance in a concentration of 10mg/ml" is not a positive claim limitation as it is not a required limitation as the claims are only drawn to the agent itself.

7. Claims 1-3, 5-6 and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Fahy et al (US Patent No. 6,395,467 B1).

The reference teaches, in the claims, a cryoprotectant solution comprising: dimethyl sulfoxide, an amide selected from the group consisting of formamide, urea, acetamide, hydroxyurea and N-methyl formamide, and ethylene glycol or ethylene glycol in combination with propylene glycol wherein the propylene glycol replaces less than 8% w/v of the ethylene glycol. It may further comprise: a polymeric material selected from the group consisting of: ficol, polyethylene glycol, polyvinylpyrrolidone, and polyvinyl alcohol, said polymeric material ranging from about 800 daltons to about 5,000 daltons as a non-penetrating agent for facilitating vitrification and inhibiting devitrification in vitrification solutions, wherein said polymeric material is hydrophillic and nontoxic. See also Table 6. Column 2, lines 48+, teach that the solutions are for cryopreservation of cells, tissues, organs, artificial organs, artificial tissues, and non-living biological systems. The invention also provides specific families of freezing solutions based on the new vitrification solutions. Further the invention provides cryoprotectant solutions and methods that also have applications in preservation by freezing point depression, supercooling, and cold storage.

The instant claims appear to be met by the reference as they teach the formation of various non-proteinaceous agents for inhibition of ice-crystal growth. As for the properties recited in the claims, these appear to be inherent properties possessed by the agents of the reference absent evidence showing otherwise. Applicant should note that the limitation of "wherein an aqueous solution of the non-proteinaceous substance in a concentration of 10mg/ml" is not a positive claim limitation as it is not a required limitation as the claims are only drawn to the agent itself.

8. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Wowk (US Patent No. 6,391,224 B1).

The reference teaches in the abstract and the claims, polyvinyl alcohol compounds for inhibition of ice growth. These polyvinyl alcohol additives are very useful for enhancing the performance of antifreeze formulations, biological cryopreservation solutions, and for preventing frost damage to plants and other industrial products and processes. Column 5, lines 48+, teaches that in one embodiment, PVA compounds can be included in water sprays that are used to spray the surface of plants at acute risk of freezing. In another embodiment, PVA compounds can be included in normal irrigation water on a long-term basis. In another embodiment, low molecular weight PVA compounds might be included in irrigation water, fertilizer formulations, or plant potting soil so that these compounds are absorbed by plants to provide freezing protection inside plant tissues. In another embodiment, PVA compounds might be dispersed in the form of a powder on plants. In still another embodiment, PVA can be included as a component of other antifreeze solutions used for plant frost protection. In addition to inhibition of plant freezing, it is also anticipated that PVA compounds might inhibit freezing of animal or human peripheral tissue that is subjected to cold temperatures. In another embodiment, the PVA compounds might simply be included in cleansing products for the purpose of removing INA material from skin before cold exposure.

The instant claims appear to be met by the reference as they teach the formation of various non-proteinaceous agents for inhibition of ice-crystal growth. As for the properties recited in the claims, these appear to be inherent properties possessed by the agents of the reference absent evidence showing otherwise. Applicant should note that the limitation of "wherein an aqueous solution of the non-proteinaceous substance in a concentration of 10mg/ml" is not a positive claim limitation as it is not a required limitation as the claims are only drawn to the agent itself.

9. Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Fahy (US Patent No. 6,773,877 B2) (patent equivalent to US Patent Application Publication 2003/0111638 which was cited by applicants).

The reference teaches, in the abstract, examples and the claims, a method of inhibiting growth of ice crystals, comprising: identifying a material requiring inhibition of growth of ice crystals, and applying to said material a plurality of molecules in an amount effective for inhibiting ice crystal growth on or in said material; wherein said molecules are selected from the group consisting of CH.sub.3 $(CHOH(CH_2)_3)_nCH_3$, wherein n is 2 to 3,000, 1,3-cyclohexanediol, cis,cis-1,3,5-cyclohexanetriol, etc. Column 21, lines 30+, teaches the types of materials that may be treated with the ice inhibitor which include, treating crops by spraying, addition to food, cryoprotective solutions for tissues etc.

The instant claims appear to be met by the reference as they teach the formation of various non-proteinaceous agents for inhibition of ice-crystal growth. As for the

properties recited in the claims, these appear to be inherent properties possessed by the agents of the reference absent evidence showing otherwise. Applicant should note that the limitation of "wherein an aqueous solution of the non-proteinaceous substance in a concentration of 10mg/ml" is not a positive claim limitation as it is not a required limitation as the claims are only drawn to the agent itself.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anthony J. Green whose telephone number is 571-272-1367. The examiner can normally be reached on Monday-Thursday 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorengo can be reached on 571-272-1233. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anthony J. Green/

Primary Examiner
Art Unit 1793

ajg
April 11, 2008